

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**Address: COMMISSIONER OF PATENTS AND TRADEMARKS
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/700,713 11/27/00 SOMA

G 101149-00008

EXAMINER

HM22/0601

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ART UNIT PAPER NUMBER

1645

DATE MAILED:

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)
	09/700,713	SOMA ET AL.
	Examiner	Art Unit
	Khatol S Shahnan-Shah	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 27 November 2000 and 8 May 2001.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-16 is/are pending in the application.

4a) Of the above claim(s) 13-14 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-12, 15 and 16 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims 1-16 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) Notice of References Cited (PTO-892) 18) Interview Summary (PTO-413) Paper No(s). _____

16) Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) Notice of Informal Patent Application (PTO-152)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 20) Other: _____

Detailed Action

1. Applicants' preliminary amendment, received November 27, 2000, paper # 3 is acknowledged.

Election/Restrictions

2. Applicants' election with traverse of May 8, 2001 in Paper No. 5 is acknowledged. The traversal is on the ground(s) that searching for group II will not put additional burden upon the office when searching for elected group I, has been noted. This is not found persuasive because while the searches may overlap but they are not coextensive. Because Groups I and II are drawn to two different specifically and technically distinct features. The claims of group I are drawn to a food additive for fish and crustaceans. Those of group II are drawn to a method of breeding for fish or crustaceans which encompass distinct process and methods.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 13-14, are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to non elected group II.
4. Currently claims 1-12 and 15-16 are pending and under consideration.

Title

5. The title of the disclosure is not descriptive and objected to because of the recitation "Additives for crustacean or fish feeds and feeds". It is not clear what the applicants mean by reciting feeds and feeds. Correction is required.

Priority

6. Acknowledgment is made of applicants' claim for foreign priority based on an application number 84399 filed in Japan on 3/26/1999. It is noted, however, that applicants have not filed a

translated copy of the above application. A claim for priority under 35 U.S.C. 119(a)-(d) cannot be based on said application, until the receipt of the translated copy by the PTO.

7. Complete priority statement is missing from specification:

This application filed under former 37 CFR 1.62 lacks the necessary reference to the prior application(s). A statement reading " This is a U.S.C. 371 of Application of PCT/JP00/01764 filed on March 23,2000 and claims priority to Japanese application No. 84399, filed on March 26,1999" should be entered following the title of the invention or as the first sentence of the specification. Also, the current status of the parent nonprovisional application(s) should be included. The preliminary amendment received on 11/27/2000 does not address the complete above statement.

Specification Informalities

8. The disclosure is objected to because of the following informalities:

Specification page 6, line 28 the word disease is spelled “decease”. Appropriate correction is required.

Specification page 10 lines 21-23, it is unclear what applicants mean by stating Pantoea agglomerans-carrying bacteria. Please explain and correct.

The use of the trademark has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks. Specification page 16 line 13, the trademark “Eukitt” is used without the trademark sign and generic terminology.

Applicants' cooperation is requested to review the entire specification for all possible errors and correct any errors of which applicants may become aware in the specification.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claims 3 and 7 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, delimiting how this use is actually practiced. Without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim, which is not a proper process, claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim 3 provides for the use of a low molecular weight lipopolysaccharide for the preparation of a feedstuff additive for fish, but since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass.

Claim 7 provides for the use of the same low molecular lipopolysaccharide for the preparation of an agent to prevent perish of fish, but since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1-12 and 15-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for 3 species of crustaceans and fish, but not for all crustaceans and fish and does not reasonably provide enablement for any other embodiment encompassed by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to identify or make the invention commensurate in scope with these claims. Enablement is considered in view of the Wands factors (MPEP) 2164.01(a).

Nature of the invention: The invention is directed to a feedstuff additive, which is capable of activating immunity or preventing infection in crustaceans or fish.

Breadth of the claims: The claims are extremely broad, encompassing any species of crustaceans and fish.

Working examples: Only three working examples given in the specification. Kuruma prawns, black carps and yellowtails are used in the examples, these species do not encompass all crustaceans or fish.

Applicants claim more than 15 different kind of infectious diseases in claim 15. The only working examples of the claimed diseases given in the specification are acute viremia of crustaceans caused by PRDV (penaeid rod-shaped DNA virus) and disease caused by *Enterococcus seriolicida* in yellowtails. Even the elected “vivro diseases” of crustaceans has not been described by the examples.

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Guidance in specification: The specification provides only three working examples of species and two examples of the infectious diseases, which is not considered enough guidance regarding practice of the claimed methods.

State of the prior art: Investigation of the feedstuff additives to prolong life and provide safe fish products is well known in the art and has been used in fishery industry for years.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

11. Claims 1-12 and 15-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite, because contain numerous grammatical errors. Such as:

“the perish”, “infectious diseases is”, “streptococcic diseases”.

The term "substantially" in claim 1 is a relative term, which renders the claim indefinite because it is unclear what constitutes the metes and bounds of those encompassed by “substantially free of high molecular weight lipopolysaccharide”.

Claim 15 recites the limitation "infectious diseases" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 15 is indefinite, because in lines 3 and 6 recites “vivrio diseases”. It is unclear what the applicants mean by this recitation, please elaborate.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-12 and 16 are rejected under U.S.C. 102(b) as being anticipated by Soma et al. (US Patent No. 5,346,891).

Claims 1-12 and 16 are drawn to a product prepared from gram negative bacteria, that has a molecular weight of 5000 ± 2000 as measured by SDS-PAGE method. That the product is a low molecular weight lipopolysaccharide and capable of activating immunity or prevent infection. The product is intended to be used as a feedstuff additive for crustaceans and fish.

However, intended use does not impart any critical impact or weight on the physical preparation and the patentability of the product.

Soma et al. disclosed three products (novel lipopolysaccharides) from gram negative bacteria that had molecular weights of $5,000 \pm 1000$ and $6,500 \pm 2,500$ as measured by SDS-PAGE method. (see abstract and claims). The products has been used as immunity stimulators via oral administration for different animals. (see column 18 lines, 25-60 and claims 4-6). One of the lipopolysaccharide is produced by a strain of the species *Pantoea agglomerans* (see claim 3). Since the office does not have the facilities for examining and comparing applicants' product with the product of the prior art, the burden is on the applicant to

show a novel or unobvious difference between the claimed product and the product of the prior art (i. e., that the product of prior art does not possess the same material structure and functional characteristics of the claimed product). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a), which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 1-12 and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yabiki et al. (US Patent No. 5,268,357) in view of Rorstad et al. (US Patent No. 5,401,727) and further in view of Soma et al. (US Patent No. 5,494,819).

Claims 1-12 and 15-16 are drawn to a feedstuff additive prepared from gram negative bacteria, that is capable of activating immunity or preventing infection in crustaceans and fish.

Yabiki et al. teach feed and feed additive for fishes and other animals for increasing disease resistance. (see title and abstract). They used a combination of bile powder and peptidoglycan from cell wall of gram positive bacteria. (see claim 1). The feed was added to commercial feed for rainbow trout (see embodiment No. 6). They also tested their product to prevent viral diseases. Yabiki et al. did teach the use of their product to prevent disease in crustaceans.

Rorstad et al. teach a process and product for enhancing the resistance of aquatic animals to disease (see title and abstract). They teach a process for stimulating the immune system of aquatic animals of the class Osteichytes and subphylum of Crustacea using yeast cell wall glucan. They studied different fish and crustaceans species and their vibrio and aeromonas diseases. (see examples II- X). Rorstad et al. did not teach gram negative bacteria.

Soma et al. (US patent No. 5,494,819) teach a pure culture of *Pantoea agglomerans* and its lipopolysaccharide with a molecular weight of $6,500 \pm 2,500$ (see abstract) and 5000 ± 1000 (column 10 lines 35-36) having immunity stimulating effects (see experiment 1)

It would have been *prima facie* obvious to a person skilled in the art at the time the invention was made to modify and combine the methods and products taught by Yabiki et al. and Rorstad et al. with the product taught by Soma et al. to obtain the disclosed invention. One having ordinary skill in the art would have been motivated to replace the high molecular weight molecules of Yabiki et al. and Rorstad et al. with the low molecular weight lipopolysaccharide of Soma et al. because generally low molecular weight polysaccharides will be better absorbed.

14. Claims 1-12 and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takahashi et al. (US Patent No. 5,641,761) in view of Matsuyama et al. (Aquaculture, 101,1997) and further in view of Soma et al. (US Patent No. 5,494,819).

Claims 1-12 and 15-16 are drawn to a feedstuff additive prepared from gram negative bacteria, that is capable of activating immunity or preventing infection in crustaceans and fish.

Takahashi et al. teach a preventive agent (feedstuff) against infectious diseases of crustaceans comprising of a glucan from fungi. (see title and abstract). They tested their product on Kuruma prawns (see examples 1-7). They teach a method of enhancing the immune system

of crustaceans by feeding them a water-soluble form of their product (see claim 1). They also teach a method of treating crustaceans' infections such as vibrio infections, mycotic infections, and viral infections by feeding them their product. Takahashi et al. did not teach infections in fish. However Matsuyama et al. teach the use of a glucan derived from schizophyllum commune (a fungus) against Streptococcal infection of yellowtails.

Soma et al. (US patent No. 5,494,819) teach a pure culture of *Pantoea agglomerans* and its lipopolysaccharide with a molecular weight of $6,500 \pm 2,500$ (see abstract) and 5000 ± 1000 (column 10 lines 35-36) having immunity stimulating effects (see experiment 1)

It would have been *prima facie* obvious to a person skilled in the art at the time the invention was made to modify and combine the products taught by Takahashi et al. and the method by Matsuyama et al. with the product taught by Soma et al. to obtain the disclosed invention. One having ordinary skill in the art would have been motivated to replace the high molecular weight molecules of Takahashi et al. and Matsuyama et al. with the low molecular weight lipopolysaccharide of Soma et al. because generally low molecular weight polysaccharides will be better absorbed.

Conclusion

15. No claim allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shahnan-Shah whose telephone number is (703) 308-8896. The examiner can normally be reached from 7: 30 AM - 4 PM on Monday through Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith,

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can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned to is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Khatol Shahnan-Shah 5/25/01

Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

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RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER